AUTOMATED MEDICAL INFUSION DEVICE AND METHOD WITH IMPROVED ACCURACY AND SAFETY CHARACTERISTICS AND MRI-SAFE CAPABILITY

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority benefit of pending provisional application U.S. 62/435,991 filed Dec. 19, 2016, and also of pending provisional application U.S. 62/558,266 filed Sep. 13, 2017. These priority applications are hereby incorporated by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] The present invention is in the field of medical drug and fluid infusion, in particular the delivery to a patient, typically by intravenous infusion, of fluid from bags or bottles. Further, the field of this invention includes, but is not limited to, delivery of fluid to a patient, typically by intravenous infusion, in environments where use of ferrous and magnetic materials must be minimized.

[0003] Intravenous delivery of drugs and other fluids to patients is a common and important medical practice. For delivery of larger fluid quantities, typically over 100 mL, these fluids are typically delivered from a container in the form of a sterile bag or bottle. Usually the bag or bottle is hung from a pole or rack at a height somewhat above the seated or prone patient. Connection between the container and patient is made with an IV set. This is most basically a long, flexible polymer tube with a spike fitting at one end and a Luer fitting at the other. The spike is used to make a sealed, sterile connection to the fluid container; a hypodermic needle is mounted to the Luer fitting to deliver the fluid to the patient's venous system. The IV set may also incorporate various other elements including clamps, valves, filters, additional ports.

[0004] It is important for both safety and efficacy to provide control of the flow of fluid from the container to the patient. The flow requirement is typically specified as a flow rate with units of milliliters per minute or milliliters per hour, but may also be specified as a total delivery time and volume. A variety of methods have been developed to provide accurate and reliable control of the flow.

[0005] The oldest and most basic method uses gravity to drive the flow. With the container located above the patient there is a static pressure $\Delta P = \rho g h$, where ρ is the density of the fluid, g is the acceleration of gravity, and h is the height of the container relative to the patient. Due to this pressure fluid will move from the container to the patient at a rate determined by the geometry of the IV set. For typical use a drip chamber is used to measure the flow rate. The drip chamber is typically positioned just below the spike on the IV set, but may also be placed at an intermediate position along the tube of the IV set. The drip chamber is a clear plastic tube, usually 1-2 centimeter diameter and 5-10 centimeter length, closed at both ends and, for use, oriented vertically. Fluid enters at the top of the drip chamber and passes through a small nozzle. It falls from the nozzle as individual drops. The drops land in a small pool of fluid at the bottom of the drip chamber and the fluid then passes into the connecting tube to the patient. The nozzle is constructed such each drop will be of a known volume, typically 0.1, 0.05, or 0.017 mL. A clinician can look through the clear wall of the drip chamber and view the drops as they form and fall. A close estimate of the flow rate can be made by using the known volume per drop and by counting either the time between drops or the number of drops in a fixed time interval.

[0006] To control the flow a manually-operated, adjustable clamp is placed on the tube at a point below the drip chamber. The clamp acts to flatten and partially occlude a short portion of the tube, increasing the resistance to fluid flow. The clinician adjusts this clamp and notes the effect on the drop rate. With some skill the clinician can make a series of adjustments to produce a desired drop rate and so, in turn, a desired flow rate or delivery time.

[0007] Manually-controlled gravity-driven infusion, using a drip chamber for measurement and an adjustable clamp for control, is simple and inexpensive. It has been in widespread use since the 1950's and continues to be used for some non-critical applications and where low cost is an overriding factor. In other cases it has been superseded because of several critical limitations:

[0008] Setting the flow rate is time-consuming and not very accurate. The setting requires repeated trial-and-error adjustments while manually counting drops.

[0009] After the initial setting there is no ongoing measurement or control so the flow rate may vary over time as, for example, the fluid level drops in the container, the fluid temperature changes, or the flexible tube re-conforms in the area under the clamp. The last item is most critical, the polymer tube will re-conform over time to relieve applied stress; this can lead to either an increase or decrease in flow rate.

[0010] Being completely manual this method cannot generate a signal or alarm when a dose has been completed or if there is a problem such as a blockage that prevents flow. Unsafe conditions cannot be detected and the flow cannot automatically be stopped if there is an unsafe condition or if a desired total dose has been delivered.

[0011] There is no automation to verify dosage or flow rates. All steps and calculations are performed manually, so there is a high likelihood of human error.

[0012] Since the 1970's infusion pumps have replaced manually-controlled, gravity-driven infusion for many applications. The pumps are of various types, but share the important characteristic that they have a pumping chamber built in to the disposable IV set. This is necessary to maintain sterility of the fluid path. The pump mechanism works externally to this sterile pumping chamber to pump a nominally constant volume of fluid during each pumping cycle. The volume pumped per cycle varies from about 0.1 mL to 2 mL per cycle. Most pumps are either of the peristaltic type, which use rollers or moving fingers to push fluid along a length of flexible tubing, or diaphragm type, which have a flexible diaphragm or bulb that is pressed to move fluid and a set of valves to control the direction of fluid movement. Modern infusion pumps are computer controlled and have a sophisticated user interfaces and programming. They are designed to assist with rate and dosage setting, prevent certain user errors, and detect and respond to certain unsafe conditions during operation.

[0013] Infusion pumps also have several limitations, which are different than those encountered with gravity-driven infusion: